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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,793	11/18/2003	Debbie Yaver	10351.200-US	8797
25907	7590	08/22/2006	EXAMINER	
NOVOZYMES, INC. 1445 DREW AVE DAVIS, CA 95616			JOIKE, MICHELE K	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 08/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,793	<b>Applicant(s)</b> YAVER ET AL.	
	<b>Examiner</b> Michele K. Joice, Ph.D.	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 10, 25-28, 30, 31, 53, 62, 77-80, 82, 83 and 87-90 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 27, 28, 53, 77, 79, 80 and 87-90 is/are rejected.
- 7) ☒ Claim(s) 10, 25, 30, 31, 62, 82 and 83 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/05/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group IV in the reply filed on October 31, 2005 is acknowledged. The traversal is on the ground(s) that Groups IV and XV both involve the promoter variant SEQ ID NO: 5. This argument is found persuasive, and Groups IV and XV are rejoined. However, claims 26 and 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 31, 2005. Applicant's election with traverse of the species election of a hybrid promoter comprised of SEQ ID NO: 5 and SEQ ID NO: 3 in the reply filed on October 31, 2005 is acknowledged. The traversal is on the ground(s) that a hybrid promoter can comprise a portion of one or more promoters of the present invention, a portion of a promoter of the present invention and a portion of another promoter or a portion of one or more promoters of the present invention and a portion of one or more promoters, which places a severe burden on Applicant to realize the full scope of protection. This is not found persuasive because a hybrid promoter can comprise a portion of one or more promoters. The hybrid promoters are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: in the instant case, the claims are related because all of the groups contain nucleotide sequences, however, each group involves products not required by the other so that groups are not linked by a single feature. Distinctly different nucleotide sequences are

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structurally distinct chemical compounds and are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) sequence, or in this a single combination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 26 and 78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 31, 2005.

Claims 1, 10, 25, 26, 27, 28, 30, 31, 53, 62, 77, 78, 79, 80, 82, 83, 87, 88, 89, and 90 are pending. Claims 1, 10, 25, 27, 28, 30, 31, 53, 62, 77, 79, 80, 82, 83, 87, 88, 89, and 90 are under examination.

### ***Specification***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

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and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Figures 1A and 1B contain nucleotide sequences that need a sequence identifier.

### ***Claim Objections***

Claims 1, 25, 28, 31, 53, 77, 80, and 83 are objected to because of the following informalities: The claims contain nonelected sequences. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 77 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 77 recites the limitation "the first nucleic acid sequence" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

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by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 27, 28, 53, 79, 80, 87, 88, 89 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,361,973.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants claim a method for producing a biological substance comprising cultivating a fungal host cell that comprises a first nucleic acid sequence encoding the biological substance operably linked to a second nucleic acid sequence comprising a promoter variant, SEQ ID NO: 5, subsequences thereof, and hybrid promoters, thereof, and isolating the biological substance. The hybrid promoter is comprised of portions of two or more promoters, specifically SEQ ID NOs: 3 and 5. Also claimed is the promoter variant of SEQ ID NO: 5, subsequences thereof, and hybrid promoters thereof, a nucleic

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acid construct encoding the biological substance operably linked to a second nucleic acid sequence comprising a promoter variant, SEQ ID NO: 5, subsequences thereof, and hybrid promoters, thereof, a vector comprising the nucleic acid construct, and a host cell comprising the nucleic acid construct. The hybrid promoter is comprised of portions of two or more promoters, specifically SEQ ID NOs: 3 and 5. Lastly, a method for producing a biological substance comprising a recombinant cell comprising a promoter variant, an exon, and/or a splice donor site operably linked to a second exon encoding the biological substance and recovering the substance, is claimed.

US 6,361,973 (specifically abstract, columns 1, 2, 10 and 11 and SEQ ID NO: 1) teach a method for producing a biological substance comprising cultivating a fungal host cell that comprises a first nucleic acid sequence encoding a polypeptide operably linked to a second nucleic acid sequence comprising a promoter, SEQ ID NO: 1, subsequences thereof, and hybrid promoters, thereof, and isolating the polypeptide. Also taught is the promoter, SEQ ID NO: 1, subsequences thereof, and hybrid promoters thereof, a nucleic acid construct encoding the polypeptide operably linked to a second nucleic acid sequence comprising a promoter, SEQ ID NO: 1, subsequences thereof, and hybrid promoters, thereof, a vector comprising the nucleic acid construct, and a host cell comprising the nucleic acid construct. Lastly, a method for producing a polypeptide comprising a recombinant cell comprising a promoter variant, an exon, and/or a splice donor site operably linked to a second exon encoding the polypeptide and recovering the polypeptide, is taught.

SEQ ID NO: 1 is not 100% identical to SEQ ID NO: 5, but fits the definition of being a subsequence. Subsequence is defined by Applicant in the specification as being at least about 1200 nucleotides. SEQ ID NO: 1 has a match of 1089 nucleotides to SEQ ID NO: 5, which is a less than 10% difference, so is therefore fits the definition of a subsequence that is at least about 1200 nucleotides. SEQ ID NO: 1 also is not 100% identical to SEQ ID NO: 3, but fits the definition of being a subsequence. Subsequence is defined by Applicant as being at least about 1200 nucleotides. SEQ ID NO: 1 has a match of 1089 nucleotides to SEQ ID NO: 3, which is a less than 10% difference, so is therefore fits the definition of a subsequence that is at least about 1200 nucleotides. Portions SEQ ID NO: 3 and 5 are present in SEQ ID NO:1, therefore SEQ ID NO: 1 also fits the definition of a hybrid promoter.

#### ***Allowable Subject Matter***

Claims 10, 30, 62 and 82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

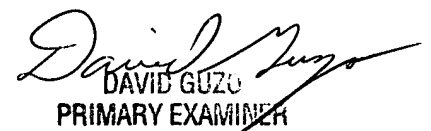


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER